Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

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Foreword - Purpose for National Coverage Determinations Manual

A - Purpose

(Rev. 1, 10-01-03)

The statutory and policy framework within which National Coverage Decisions are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The National Coverage Determinations Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on §1862(a)(1) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial. Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions

The coverage decisions in the manual will be kept current, based on the most recent medical and other scientific and technical advice available to CMS.

Other manuals in this system in which coverage-related instructions may be found are:

Pub 100-2 (Benefit Policy);

Pub 100-4 (Claims Processing);

Pub 100-5 (Medicare Secondary Payer); and

Pub 100-8 (Program Integrity)

These manuals usually contain more general coverage descriptions and/or processing instructions. There should be no inconsistencies among the instructions in any of these manuals and the National Coverage Determinations Manual. If any such inconsistencies are found, bring them to the attention of CMS, OSORA.

B - Organization

The NCD manual is organized by categories, e.g., Medical Procedures, Supplies, Diagnostic Services. A Table of Contents is provided at the beginning of the manual

designating coverage decision categories. Each subject discussed within the category is listed and identified by a number.

The revision transmittal sheet identifies new material and summarizes the principal changes. When a change in policy or procedure is involved, the background and effective date for the change is provided. If, at a later date, the reader wishes to refer to the background explanation given on a transmittal sheet, the reader can identify the transmittal by its number which appears on each manual page.

C - CMS Coverage Web site

The CMS Coverage Web page http://www.cms.hhs.gov/medcov contains information about pending National Coverage Determinations and also provides access to a database of National Coverage Determinations, National Coverage Analyses, and Local Medical review Policies.

10 - Anesthesia and Pain Management - Not Yet Available

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10.2 - Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain - Not Yet Available

10.3 - Inpatient Hospital Pain Rehabilitation Programs - Not Yet Available

10.4 - Outpatient Hospital Pain Rehabilitation Programs - Not Yet Available

10.5 - Autogenous Epidural Blood Graft - Not Yet Available

10.6 - Anesthesia in Cardiac Pacemaker Surgery - Not Yet Available

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20.4 - Implantable Automatic Defibrillators - Not Yet Available

20.5 - Extracorporeal Immunoadsorption (ECI) Using Protein A Columns - Not Yet Available

20.6 - Transmyocardial Revascularization (TMR) - Not Yet Available

20.7 - Percutaneous Transluminal Angioplasty (PTA) - Not Yet Available

20.8 - Cardiac Pacemakers - Not Yet Available

20.8.1 - Cardiac Pacemaker Evaluation Services - Not Yet Available

20.8.1.1 - Transtelephonic Monitoring of Cardiac Pacemakers - Not Yet Available

20.8.2 - Self-Contained Pacemaker Monitors - Not Yet Available

20.8.3 - Anesthesia in Cardiac Pacemaker Surgery - Not Yet Available

20.9 - ARTIFICIAL HEARTS AND RELATED DEVICES

(Rev2, 10-17-03)

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or as destination therapy.

A. Covered Indications

*1. **Postcardiotomy (effective for services performed on or after October 18, 1993)***

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA- approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)

VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and,

b. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

3. Destination Therapy (effective for services performed on or after October 1, 2003)

*Destination therapy is for patients that require permanent mechanical cardiac support. VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet **all** of the following conditions:*

a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;

b. The patient has a left ventricular ejection fraction (LVEF) < 25%;

*c. The patient has demonstrated functional limitation with a peak oxygen consumption of < 12 ml/kg/min; **or** the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; **and**,*

d. The patient has the appropriate body size (≥ 1.5 m²) to support the VAD implantation.

In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that VAD implantation as destination therapy is reasonable and necessary only when the procedure is performed in a Medicare-approved heart transplant facility that, between January 1, 2001, and September 30, 2003, implanted at least 15 VADs as a bridge-to-transplant or as destination therapy. These devices must have been approved by the FDA for destination therapy or as a bridge-to-transplant, or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications. VADs implanted for other investigational indications or for support of blood circulation post-cardiotomy do not satisfy the volume requirement for this purpose. Since the relationship between volume and outcomes has not been well-established for VAD use, facilities that have minimal deficiencies in meeting this standard may apply and include a request for an exception based upon additional factors. Some of the factors CMS will consider are geographic location of the center, number of destination procedures performed, and patient outcomes from VAD procedures completed.

Also, this facility must be an active, continuous member of a national, audited registry that requires submission of health data on all VAD destination therapy patients from the date of implantation throughout the remainder of their lives. This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer. The registry must also provide such routine reports as may be specified by CMS, and must have standards for data quality and timeliness of data submissions such that hospitals failing to meet them will be removed from membership. CMS believes that the registry sponsored by the International Society for Heart and Lung Transplantation is an example of a registry that meets these characteristics.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

CMS plans to develop accreditation standards for facilities that implant VADs and, when implemented, VAD implantation will be considered reasonable and necessary only at accredited facilities.

A list of facilities eligible for Medicare reimbursement for VADs as destination therapy will be maintained on our website and available at www.cms.hhs.gov/coverage/lvadfacility.asp. In order to be placed on this list, facilities must submit a letter to the Director, Coverage and Analysis Group, 7500 Security Blvd, Mailstop C1-09-06, Baltimore, MD 21244. This letter must be received by CMS within 90 days of the issue date on this transmittal. The letter must include the following information:

- **Facility's name and complete address;**
- **Facility's Medicare provider number;**
- **List of all implantations between Jan. 1, 2001, and Sept. 30, 2003, with the following information:**
    - **Date of implantation,**
    - **Indication for implantation (only destination and bridge-to-transplant can be reported; post-cardiotomy VAD implants are not to be included),**
    - **Device name and manufacturer, and,**
    - **Date of device removal and reason (e.g., transplantation, recovery, device malfunction), or date and cause of patient's death;**
- **Point-of-contact for questions with telephone number;**
- **Registry to which patient information will be submitted**; and,
- **Signature of a senior facility administrative official.**

Facilities not meeting the minimal standards and requesting exception should, in addition to supplying the information above, include the factors that they deem critical in requesting the exception to the standards.

CMS will review the information contained in the above letters. When the review is complete, all necessary information is received, and criteria are met, CMS will include the name of the newly Medicare-approved facility on the CMS web site. No reimbursement for destination therapy will be made for implantations performed before the date the facility is added to the CMS web site. Each newly approved facility will also receive a formal letter from CMS stating the official approval date it was added to the list.

B. Noncovered Indications (effective for services performed on or after May 19, 1986)

1. Artificial Heart

Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the human heart, Medicare does not cover this device when used as an artificial heart.

2. All other indications for the use of VADs not otherwise listed remain noncovered, except in the context of Category B IDE clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD manual (old CIM 30-1).

(This NCD last reviewed October 2003.)

20.10 - Cardiac Rehabilitation Programs - Not Yet Available

20.11 - Intraoperative Ventricular Mapping - Not Yet Available

20.12 - Diagnostic Endocardial Electrical Stimulation (Pacing) - Not Yet Available

20.13 - HIS Bundle Study - Not Yet Available

20.14 - Plethysmography - Not Yet Available

20.15 - Electrocardiographic Services - Not Yet Available

20.16 - Cardiac Output Monitoring by Electrical Bioimpedance - Not Yet Available

20.17 - Noninvasive Tests of Carotid Function - Not Yet Available

20.18 - Carotid Body Resection/Carotid Body Denervation - Not Yet Available

20.19 - Ambulatory Blood Pressure Monitoring - Not Yet Available

20.20 - External Counterpulsation (ECP) for Severe Angina - Not Yet Available

20.21 - Chelation Therapy for Treatment of Atherosclerosis - Not Yet Available

20.22 - Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis - Not Yet Available

20.23 - Fabric Wrapping of Abdominal Aneurysms - Not Yet Available

20.24 - Displacement Cardiography - Not Yet Available

20.25 - Cardiac Catheterization Performed in Other Than a Hospital Setting - Not Yet Available

20.26 - Partial Ventriculectomy - Not Yet Available

20.27 - Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test - Not Yet Available

20.28 – Therapeutic Embolization - Not Yet Available

20.29 – Hyperbaric Oxygen Therapy - Not Yet Available

30 - Complementary and Alternative Medicine - Not Yet Available

30.1 - Biofeedback Therapy - Not Yet Available

30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence - Not Yet Available

30.2 - Thermogenic Therapy - Not Yet Available

30.3 - Acupuncture - Not Yet Available

30.4 - Electrosleep Therapy - Not Yet Available

30.5 - Transcendental Meditation - Not Yet Available

30.6 - Intravenous Histamine Therapy - Not Yet Available

30.7 - Laetrile and Related Substances - Not Yet Available

30.8 - Cellular Therapy - Not Yet Available

30.9 - Transillumination Light Scanning, or Diaphanography - Not Yet Available

40 - Endocrine System and Metabolism - Not Yet Available

40.1 - Diabetes Outpatient Self-Management Training - Not Yet Available

40.2 - Home Blood Glucose Monitors - Not Yet Available

40.3 - Closed-Loop Blood Glucose Control Device (CBGCD) - Not Yet Available

40.4 - Insulin Syringe - Not Yet Available

40.5 - Treatment of Obesity - Not Yet Available

50 - Ear, Nose, and Throat (ENT)

(Rev. 1, 10-01-03)

50.1 - Speech Generating Devices

(Rev. 1, 10-01-03)

CIM 60-23

Effective January 1, 2001, augmentative and alternative communication devices or communicators which are hereafter referred to as "speech generating devices" are now considered to fall within the DME benefit category established by §1861(n) of the Act. They may be covered if the contractor's medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating are characterized by:

- Being a dedicated speech device, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- May have synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- May have synthesized speech output which permits multiple methods of message formulation and multiple methods of device access; or
- May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) of the Act are characterized by:

- Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that

can also run a word processing package, an accounting program, or perform other than non-medical function.

- Laptop computers, desktop computers, or PDA's which may be programmed to perform the same function as a speech generating device, are noncovered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech-generating devices for Medicare coverage purposes.

- A device that is useful to someone without severe speech impairment is not considered a speech-generating device for Medicare coverage purposes.

50.2 - Electronic Speech Aids

(Rev. 1, 10-01-03)

CIM 65-5

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

50.3 - Cochlear Implantation

(Rev. 1, 10-01-03)

CIM 65-14

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

Medicare coverage is provided only for those patients who meet **all** of the following selection guidelines.

A - General

- Diagnosis of bilateral severe-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;

- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;

- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

- No contraindications to surgery; and

- The device must be used in accordance with the FDA-approved labeling.

B - Adults

Cochlear implants may be covered for adults (over age 18) for prelinguistically, perilinguistically, and postlinguistically deafened adults. Postlinguistically deafened adults must demonstrate test scores of 30 percent or less on sentence recognition scores from tape recorded tests in the patient's best listening condition.

C - Children

Cochlear implants may be covered for prelinguistically and postlinguistically deafened children aged 2 through 17. Bilateral profound sensorineural deafness must be demonstrated by the inability to improve on age appropriate closed-set word identification tasks with amplification.

50.4 - Tracheostomy Speaking Valve

(Rev. 1, 10-01-03)

CIM 65-16

A trachea tube has been determined to satisfy the definition of a prosthetic device, and the tracheostomy speaking valve is an add on to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis. As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective.

50.5 - Oxygen Treatment of Inner Ear/Carbon Therapy

(Rev. 1, 10-01-03)

CIM 35-29

Not Covered

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, is not reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

50.6 - Tinnitus Masking

(Rev. 1, 10-01-03)

CIM 35-63

A tinnitus masker is a device designed to be worn like a behind-the-ear hearing aid by persons seeking relief from tinnitus. Tinnitus is the perception of noise in the ear and/or head area. The masker produces external sounds to distract the person from the tinnitus.

By producing an external sound a few decibels above the person's audible threshold, tinnitus masking is thought to provide sufficient distraction from subjective idiopathic tinnitus to alleviate the discomfort and debilitation associated with endogenous sounds within the ear and/or head area.

Tinnitus masking is considered an experimental therapy at this time because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise induced hearing loss. Therefore, it is not covered.

50.7 - Cochleostomy With Neurovascular Transplant for Meniere's Disease

(Rev. 1, 10-01-03)

CIM 35-50

Not Covered

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrinthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular

transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

50.8 - Ultrasonic Surgery

(Rev. 1, 10-01-03)

CIM 35-4

Reimbursement may be made for ultrasonic surgery when required in the treatment of patients with severe and recurrent episodes of vertigo due to Meniere's syndrome.

This procedure utilizes a machine that produces ultrasonic waves of high intensity and frequency that selectively irradiate certain portions of the inner ear thereby destroying the tissue. The procedure is usually done under local anesthesia, and requires the services of a surgeon and another individual who is responsible for calibrating the electrical equipment, and who assists in observing certain physical changes (e.g., movement of the eyes, "nystagmus") indicative of inner ear reaction to the ultrasonic destruction. Except in rare instances the desired result is achieved with one treatment. At present, there are two different approaches being used to apply the ultrasound to the inner ear: one through the lateral semicircular canal and, more recently, a simpler approach from a technical viewpoint, through the round window.

60 - Emergency Medicine

(Rev. 1, 10-01-03)

No coverage determinations.

70 - Evaluation and Management of Patients - Office/hospital/home

(Rev. 1, 10-01-03)

70.1 - Consultations With a Beneficiary's Family and Associates

(Rev. 1, 10-01-03)

CIM 35-14

In certain types of medical conditions, including when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be appropriate are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems and not to the treatment of the family member's problems.

Cross-references:

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B,"§20.

The Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioner Billing," §10.

The Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30.

70.2 - Consultation Services Rendered by a Podiatrist in a Skilled Nursing Facility

(Rev. 1, 10-01-03)

CIM 50-8

Consultation services rendered by a podiatrist in a skilled nursing facility are covered if the services are reasonable and necessary and do not come within any of the specific statutory exclusions. Section 1862(a)(13) of the Act excludes payment for the treatment of flat foot conditions, the treatment of subluxations of the foot, and routine foot care. To determine whether the consultation comes within the foot care exclusions, apply the same rule as for initial diagnostic examinations, i.e., where services are performed in connection with specific symptoms or complaints which suggest the need for, covered services, the services are covered regardless of the resulting diagnosis. The exclusion of routine physician examinations is also pertinent and would generally exclude podiatric consultation performed on all patients in a skilled nursing facility on a routine basis for screening purposes, except in those cases where a specific foot ailment is involved. Section 1862(a)(7) of the Act excludes payment for routine physical checkups. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §90 and §100.)

70.2.1 - Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy With Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy)

(Rev. 1, 10-01-03)

CIM 50-8.1

Presently, peripheral neuropathy, or diabetic sensory neuropathy, is the most common factor leading to amputation in people with diabetes. In diabetes, sensory neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Diabetic sensory neuropathy with LOPS is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 CFR 411.15(l)(1)(i)). Foot exams for people with diabetic sensory neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every six months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

The examination includes:

1 - A patient history, and

2 - A physical examination that must consist of **at least** the following elements:

- Visual inspection of forefoot and hindfoot (including toe web spaces);

- Evaluation of protective sensation;
- Evaluation of foot structure and biomechanics;
- Evaluation of vascular status and skin integrity;
- Evaluation of the need for special footwear; and

3 - Patient education.

A - Treatment includes, but is not limited to:

- Local care of superficial wounds;
- Debridement of corns and calluses; and
- Trimming and debridement of nails.

The diagnosis of diabetic sensory neuropathy with LOPS should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating or referring for foot care for persons with LOPS.

70.3 - Physician's Office Within an Institution - Coverage of Services and Supplies Incident to a Physician's Services

(Rev. 1, 10-01-03)

CIM 45-15

Coverage of Services and Supplies Incident to a Physician's Services

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the "incident to a physician's professional service" provision (see the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1 or the Medicare Benefit PolicyManual, Chapter 15, "Covered Medical and Other Health Services," §60.1) as in any physician's office. A physician's office within an institution must be confined to a separately identified part of the facility which is used solely as the physician's office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the "office" area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in the Medicare Benefit Policy Manual, Chapters 6, §20.4.1, or Chapter 15, "Covered Medical and Other Health Services," §60.1, the contractor gives consideration to the physical proximity of the institution and physician's office. When his office is located within a facility, a physician may not be reimbursed for services, supplies, and use of equipment which fall outside the scope of services

"commonly furnished" in physician's offices generally, even though such services may be furnished in his institutional office. Additionally, make a distinction between the physician's office practice and the institution, especially when the physician is administrator or owner of the facility. Thus, for their services to be covered under the criteria in the Medicare Benefit Policy Manual, Chapter 6, §20.4.1, or the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1, the auxiliary medical personnel must be members of the office staff rather than of the institution's staff, and the cost of supplies must represent an expense to the physician's office practice. Finally, services performed by the employees of the physician outside the "office" area must be **directly** supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In **any** setting, of course, supervision of auxiliary personnel in and of itself is not considered a "physician's professional service" to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of the auxiliary personnel could be considered an incidental part). Denials for failure to meet any of these requirements would be based on §1861(s)(2)(A) of the Act.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician's personal professional services within the institution. However, in view of the opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians' services rendered under such circumstances would require careful evaluation by the carrier to assure that payment is made only for services that are reasonable and necessary.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.

70.4 - Pronouncement of Death

(Rev. 1, 10-01-03)

CIM 50-19

According to established legal principles, an individual is not considered deceased until there has been official pronouncement of death. An individual is therefore considered to have expired as of the time he/she is pronounced dead by a person who is legally authorized to make such a pronouncement, usually a physician. Reasonable and necessary medical services rendered up to and including pronouncement of death by a physician are covered diagnostic or therapeutic services.

70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures

(Rev. 1, 10-01-03)

CIM 50-28

These instructions clarify the application of the reasonable and necessary payment exclusion to diagnostic procedures, such as chest x-rays, urinalysis, etc. provided to patients upon admission to a hospital or skilled nursing facility.

The major factors which support a determination that a diagnostic procedure performed as part of the admitting procedure to a hospital or skilled nursing facility is reasonable and necessary, are:

A - The test is specifically ordered by the admitting physician (or a hospital or skilled nursing facility staff physician having responsibility for the patient where there is no admitting physician): i.e., it is not furnished under the standing orders of a physician for his patients;

B - The test is medically necessary for the diagnosis or treatment of the individual patient's condition; and

C - The test does not unnecessarily duplicate the same test performed on an outpatient basis prior to admission or performed in connection with a recent hospital or skilled nursing facility admission.

Where the contractor has not already done so, consult with the Quality Improvement Organizations (QIOs) to obtain information gathered by the QIOs on a sample basis as to whether x-rays and diagnostic tests are being specifically ordered as described under subsection (A).

80 - Eye

(Rev. 1, 10-01-03)

80.1 - Hydrophilic Contact Lens for Corneal Bandage

(Rev. 1, 10-01-03)

CIM 45-7

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bulbous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, neurotrophic keratoconjunctivitis, and for other therapeutic reasons.

Payment may be made under §1861(s)(2) of the Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Payment for the lens is included in the payment for the physician's service to which the lens is incident. Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.4 for coverage of a hydrophilic contact lens as a prosthetic device.) See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.

80.2 - Photodynamic Therapy

(Rev. 1, 10-01-03)

CIM 35-100

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular photodynamic therapy (OPT)

OPT is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see §80.3, "Photosensitive Drugs").

- Classic Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50 percent of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

- Occult Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is noncovered for patients with a diagnosis of age-related macular degeneration (AMD*)* with occult and no classic CNV lesions.

- Other Conditions - Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is noncovered. OPT with verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual contractor discretion.

80.3 - Photosensitive Drugs

(Rev. 1, 10-01-03)

CIM 45-30

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration (FDA) on April 12, 2000, and subsequently, approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug when used in conjunction with ocular photodynamic therapy (see §80.2, "Photodynamic Therapy") when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration, Verteporfin is only covered with a diagnosis of neovascular age-related macular degeneration (ICD-9-CM 362.52) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50 percent of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (CPT code 92235). Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. OPT with verteporfin is covered for the above indication and will remain noncovered for all other indications related to AMD (see §80.2). OPT with Verteporfin for use in non-AMD conditions is eligible for coverage through individual contractor discretion.

80.4 - Hydrophilic Contact Lenses

(Rev. 1, 10-01-03)

CIM 65-1

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the Act and are not covered when used in the treatment of nondiseased eyes with spherical ametrophia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.1 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §100 and §120.

The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20 and §90.

80.5 - Scleral Shell

(Rev. 1, 10-01-03)

CIM 65.3

Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses.

A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue.

In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under §1861(s)(8) of the Act.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120 and §130

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §40 and §120.1.

80.6 - Intraocular Photography

(Rev. 1, 10-01-03)

CIM 35-39

Intraocular photography is covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Make Medicare payment for the use of this procedure by an opthalmologist in these situations when it is reasonable and necessary for the individual patient to receive these services.

80.7 - Refractive Keratoplasty

(Rev. 1, 10-01-03)

CIM 35-54

Not Covered

Refractive keratoplasty is surgery to reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness) and hyperopia (farsightedness). Refractive keratoplasty procedures include keratomileusis, in which the front of the cornea is removed, frozen, reshaped, and stitched back on the eye to correct either near or farsightedness; keratophakia, in which a reshaped donor cornea is inserted in the eye to correct farsightedness; and radial keratotomy, in which spoke-like slits are cut in the cornea to weaken and flatten the normally curved central portion to correct nearsightedness.

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eye glasses or contact lenses which are specifically excluded by §1862 (a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery which is excluded by §§1862 (a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

80.7.1 - Keratoplasty

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.

The use of lasers to treat ophthalmic disease constitutes opthalmalogic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.

80.8 - Endothelial Cell Photography

(Rev. 1, 10-01-03)

CIM 50-38

Endothelial cell photography involves the use of a specular microscope to determine the endothelial cell count. It is used by ophthalmologists as a predictor of success of ocular surgery or certain other ocular procedures. Endothelial cell photography is a covered procedure under Medicare when reasonable and necessary for patients who meet one or more of the following criteria:

- Have slit lamp evidence of endothelial dystrophy (cornea guttata),
- Have slit lamp evidence of corneal edema (unilateral or bilateral),
- Are about to undergo a secondary intraocular lens implantation,
- Have had previous intraocular surgery and require cataract surgery,
- Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; i.e., phacoemulsification, or refractive surgery (see §80.7 for excluded refractive procedures),
- With evidence of posterior polymorphous dystrophy of the cornea or irido-corneal-endothelium syndrome, or
- Are about to be fitted with extended wear contact lenses after intraocular surgery.

When a presurgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it. (See §10.1)

80.9 - Computer Enhanced Perimetry

(Rev. 1, 10-01-03)

CIM 50-49

Computer enhanced perimetry involves the use of a micro-computer to measure visual sensitivity at preselected locations in the visual field. It is a covered service when used in assessing visual fields in patients with glaucoma or other neuropathologic defects.

80.10 - Phaco-Emulsification Procedure - Cataract Extraction

(Rev. 1, 10-01-03)

CIM 35-9

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

80.11 - Vitrectomy

(Rev. 1, 10-01-03)

CIM - 35-16

Vitrectomy may be considered reasonable and necessary for the following conditions: vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy, and vitreous retraction. See chapter 23 of the Medicare Claims Manual for how to determine payment for physician vitrectomy services and the Medicare Claims Processing Manual, Chapter 14, "Ambulatory Surgical Centers," §40, for how to determine payment for ASC facility vitrectomy services. Also, see the Medicare Claims Processing Manual, Chapter 23, "Fee Schedule Administration and Coding Requirements," §20.9, to identify when, for Medicare payment purposes, certain vitrectomy codes are included in other codes or when codes for other services include vitrectomy codes.

The CPT codes for vitrectomy services are 67005, 67010, 67036, 67038, 67039, and 67040.

80.12 - Intraocular Lenses (IOLs)

(Rev. 1, 10-01-03)

CIM 65-7

An intraocular lens, or pseudophakos, is an artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including preimplantation ultrasound (A-scan) eye measurement of one or both eyes.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 6,"Hospital Services Covered Under Part B," §10.

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20 and §90.

90 - Genetics - Not Yet Available

100 - Gastrointestinal System

(Rev. 1, 10-01-03)

100.1 - Gastric Bypass Surgery for Obesity

(Rev. 1, 10-01-03)

CIM 35-40

Gastric bypass surgery which is a variation of the gastrojejunostomy, is performed for patients with extreme obesity. Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity.

Cross-references: §§40.5 and 100.8.

100.2 - Endoscopy

(Rev. 1, 10-01-03)

CIM 35-59

Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool, endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct.

Endoscopic procedures are covered when reasonable and necessary for the individual patient.

100.3 - 24-Hour Ambulatory Esophegeal pH Monitoring

(Rev. 1, 10-01-03)

CIM 35-83

Twenty-four hour ambulatory esophageal pH monitoring is a diagnostic procedure involving the placement of an indwelling electrode into the lower esophagus of a patient for the purpose of determining the presence of gastric reflux and measuring abnormal esophageal acid exposure.

Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

100.4 - Esophageal Manometry

(Rev. 1, 10-01-03)

CIM 50-25

Esophageal manometry is covered under Medicare where it is determined to be reasonable and necessary for the individual patient. The major use of esophageal manometry is to measure pressure within the esophagus to assist in the diagnosis of esophageal pathology including aperistalsis, spasm, achalasia, esophagitis, esophageal ulcer, esophageal congenital webs, diverticuli, scleroderma, hiatus hernia, congenital cysts, benign and malignant tumors, hypermobility, hypomobility, and extrinsic lesions. Esophageal manometry is mostly used in difficult diagnostic cases and as an adjunct to x-rays and direct visualization of the esophagus (endoscopy) through the fiberscope.

100.5 - Diagnostic Breath Analyses

(Rev. 1, 10-01-03)

CIM 50-51

Diagnostic breath analyses are tests performed to measure either the hydrogen or carbon dioxide content of the breath after the ingestion of certain compounds. The analyses are performed to diagnose certain gastrointestinal disease states.

The Following Breath Test Is Covered:

Lactose breath hydrogen to detect lactose malabsorption.

The Following Breath Tests Are Excluded From Coverage:

Lactulose breath hydrogen for diagnosing small bowel bacterial overgrowth and measuring small bowel transit time.

CO2 for diagnosing bile acid malabsorption.

CO2 for diagnosing fat malabsorption.

100.6 - Gastric Freezing

(Rev. 1, 10-01-03)

CIM 35-65

Gastric freezing for chronic peptic ulcer disease is a non-surgical treatment which was popular about 20 years ago but now is seldom done. It has been abandoned due to a high complication rate, only temporary improvement experienced by patients, and lack of effectiveness when tested by double-blind, controlled clinical trials. Since the procedure is now considered obsolete, it is not covered.

100.7 - Colonic Irrigation

CIM 35-1

Not Covered

Colonic irrigation is a procedure to wash out or lavage material on the walls of the bowel to an unlimited distance without inducing defecation. This procedure is distinguished from all types of enemas which are primarily used to induce defecation.

There are no conditions for which colonic irrigation is medically indicated and no evidence of therapeutic value. Accordingly, colonic irrigation cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

100.8 - Intestinal Bypass Surgery

(Rev. 1, 10-01-03)

CIM 35-33

Not Covered

The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure.

Cross-references: §§40.5, 100.1.

100.9 - Implantation of Anti-Gastroesophageal Reflux Device

(Rev. 1, 10-01-03)

CIM 35-69

The implantation of an anti-gastroesophageal reflux device is a surgical procedure for the treatment of gastroesophageal reflux, a condition in which the caustic contents of the stomach flow back into the esophagus. The procedure involves the implantation of this special device around the esophagus under the diaphragm and above the stomach which is secured in place by a circumferential tie strap.

The implantation of this device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment and who also:

- Have esophageal involvement with progressive systemic sclerosis; or
- Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- Are poor surgical risks for a valvuloplasty procedure; or
- Have failed previous attempts at surgical treatment with valvuloplasty procedures.

100.10 - Injection Sclerotherapy for Esophageal Variceal Bleeding

(Rev. 1, 10-01-03)

CIM 35-73

Injection sclerotherapy is a technique involving insertion of a flexible fiberoptic endoscope into the esophagus, and the injection of a sclerosing agent or solution into the varicosities to control bleeding. This procedure is covered under Medicare

100.11 - Gastric Balloon for Treatment of Obesity

(Rev. 1, 10-01-03)

CIM 35-86

Not Covered

The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety.

The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established.

100.12 - Gastrophotography

(Rev. 1, 10-01-03)

CIM 50-9

Gastrophotography is an accepted procedure for diagnosis and treatment of gastro-intestinal disorders. The photographic record provided by this procedure is often necessary for consultation and/or follow-up purposes and when required for such purposes, is more valuable than a conventional gastroscopic examination. Such a record facilitates the documentation and evaluation (healing or worsening) of lesions such as the gastric ulcer, facilitates consultation between physicians concerning difficult-to-interpret lesions, provides preoperative characterization for the surgeon, and permits better diagnosis of postoperative gastric bleeding to help determine whether there is a need for another operation. Therefore, program reimbursement may be made for this procedure.

100.13 - Laproscopic Cholecystectomy

(Rev. 1, 10-01-03)

CIM 35-91

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope). For inpatient claims, use ICD-9-CM code 51.23, Laparoscopic cholecystectomy. For all other claims, use CPT codes 47562 for laparoscopy, surgical; cholecystectomy (any method), and 47563 for laparoscopy, surgical: cholecystectomy with cholangiography.

110 - Hematology/Immunology/Oncology - Not Yet Available

110.1 - Hyperthermia for Treatment of Cancer - Not Yet Available

110.2 - Certain Drugs Distributed by the National Cancer Institute - Not Yet Available

110.3 - Anti-Inhibitor Coagulant Complex (AICC) - Not Yet Available

110.4 - Extracorporeal Photopheresis - Not Yet Available

110.5 - Granulocyte Transfusions - Not Yet Available

110.6 - Scalp Hypothermia During Chemotherapy to Prevent Hair Loss - Not Yet Available

110.7 - Blood Transfusions - Not Yet Available

110.8 - Blood Platelet Transfusions- Not Yet Available

110.8.1 - Stem Cell Transplantation - Not Yet Available

110.9 - Antigens Prepared for Sublingual Administration - Not Yet Available

110.10 - Intravenous Iron Therapy - Not Yet Available

110.11 - Food Allergy Testing and Treatment - Not Yet Available

110.12 - Challenge Ingestion Food Testing - Not Yet Available

110.13 - Cytotoxic Food Tests - Not Yet Available

110.14 - Apheresis (Therapeutic Pheresis) - Not Yet Available

110.15 - Ultrafiltration, Hemoperfusion and Hemofiltration - Not Yet Available

110.16 - Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation - Not Yet Available

120 - Infectious Diseases

(Rev. 1, 10-01-03)

No coverage determinations

130 - Mental Health - Not Yet Available

130.1 - Inpatient Hospital Stays for the Treatment of Alcoholism - Not Yet Available

130.2 - Outpatient Hospital Services for Treatment of Alcoholism - Not Yet Available

130.3 - Chemical Aversion Therapy for Treatment of Alcoholism - Not Yet Available

130.4 - Electrical Aversion Therapy for Treatment of Alcoholism - Not Yet Available

130.5 - Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic - Not Yet Available

130.6 - Treatment of Drug Abuse (Chemical Dependency) - Not Yet Available

130.7 - Withdrawal Treatments for Narcotic Addictions - Not Yet Available

130.8 - Hemodialysis for Treatment of Schizophrenia - Not Yet Available

140 - Miscellaneous Surgical Procedures

(Rev. 1, 10-01-03)

140.1 - Abortion

(Rev. 1, 10-01-03)

CIM 35-99

Abortions are not covered Medicare procedures except:

1 - If the pregnancy is the result of an act of rape or incest; or

2 - In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

This restricted coverage applies to CPT codes 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and 59866.

140.2 - Breast Reconstruction Following Mastectomy

(Rev. 1, 10-01-03)

CIM 35-47

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- A change in epidemiology of breast cancer, including an apparent increase in incidence;
- Improved surgical skills and techniques;
- The continuing development of better prostheses; and
- Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

140.3 - Transsexual Surgery

(Rev. 1, 10-01-03)

CIM 35-61

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy which may be followed by phalloplasty and the insertion of testicular prostheses. Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

140.4 - Plastic Surgery to Correct “Moon Face"

(Rev. 1, 10-01-03)

CIM 35-12

Not Covered

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient’s preoperative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of “moon face” which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

Cross reference: The Medicare Benefit Policy Manual, Chapter 16, “General Exclusions From Coverage,” §120

140.5 - Laser Procedures

(Rev. 1, 10-01-03)

CIM 35-52

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

150 - Musculoskeletal System - Not Yet Available

150.1 - Manipulation - Not Yet Available

150.2 - Osteogenic Stimulator - Not Yet Available

150.3 - Bone (Mineral) Density Studies - Not Yet Available

150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy - Not Yet Available

150.5 - Diathermy Treatment - Not Yet Available

150.6 - Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot - Not Yet Available

150.7 - Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections With Sclerosing Agents - Not Yet Available

150.8 - Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders - Not Yet Available

160 - Nervous System - Not Yet Available

160.1 - Induced Lesions of Nerve Tracts - Not Yet Available

160.2 - Treatment of Motor Function Disorders With Electric Nerve Stimulation - Not Yet Available

160.3 - Assessing Patients Suitability for Electrical Nerve Stimulation - Not Yet Available

160.4 - Steroetactic Cingulotomy as a Means of Psychosurgery - Not Yet Available

160.5 - Steroetaxic Depth Electrode Implantation - Not Yet Available

160.6 - Carotid Sinus Nerve Stimulator - Not Yet Available

160.7 - Electrical Nerve Stimulators - Not Yet Available

160.7.1 - Assessing Patients Suitability for Electrical Nerve Stimulation Therapy - Not Yet Available

160.8 - Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature - Not Yet Available

160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery - Not Yet Available

160.10 - Evoked Response Tests - Not Yet Available

160.11 - Osteogenic Stimulator - Not Yet Available

160.12 - Neuromuscular Electrical Stimulator (NMES) - Not Yet Available

160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) - Not Yet Available

160.14 - Invasive Intracranial Pressure Monitoring - Not Yet Available

160.15 - Electrotherapy for Treatment of Facial Nerve Palsy (Bell's Palsy) - Not Yet Available

160.16 - Vertebral Axial Decompression (VAX-D) - Not Yet Available

160.17 - L-Dopa - Not Yet Available

160.18 - Vagus Nerve Stimulation for Treatment of Seizures - Not Yet Available

160.19 - Phrenic Nerve Stimulator - Not Yet Available

160.20 - Transfer Factor for Treatment of Multiple Sclerosis - Not Yet Available

160.21 - Telephone Transmission of EEGs - Not Yet Available

160.22 - Ambulatory EEG Monitoring - Not Yet Available

160.23 - Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) - Not Yet Available

160.24 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease - Not Yet Available

160.25 - Multiple Electroconvulsive Therapy (MECT) - Not Yet Available

170 - Nonphysician Practitioner Services (PT/OT/SLP/Audiologists/CRNA

(Rev. 1, 10-01-03)

170.1 - Institutional and Home Care Patient Education Programs

(Rev. 1, 10-01-03)

CIM 80-1

While the Act does not specifically identify patient education programs as covered services, reimbursement may be made under Medicare for such programs furnished by providers of services (i.e., hospitals, SNFs, HHAs, and OPT providers) to the extent that the programs are appropriate, integral parts in the rendition of covered services which are reasonable and necessary for the treatment of the individual's illness or injury. For example, educational activities carried out by nurses such as teaching patients to give themselves injections, follow prescribed diets, administer colostomy care, administer medical gases, and carry out other inpatient care activities may be reimbursable as a part

of covered routine nursing care. Also, the teaching by an occupational therapist of compensatory techniques to improve a patient's level of independence in the activities of daily living may be reimbursed as a part of covered occupational therapy. Similarly, the instruction of a patient in the carrying out of a maintenance program designed for him/her by a physical therapist may be reimbursed as part of covered physical therapy.

However, when the educational activities are not closely related to the care and treatment of the patient, such as programs directed toward instructing patients or the public generally in preventive health care activities, reimbursement cannot be made since the Act limits Medicare payment to covered care which is reasonable and necessary for the treatment of an illness or injury. For example, programs designed to prevent illness by instructing the general public in the importance of good nutritional habits, exercise regimens, and good hygiene are not reimbursable under Medicare.

170.2 - Melodic Intonation Therapy

(Rev. 1, 10-01-03)

CIM 35-67

Melodic intonation therapy is a technique used in language rehabilitation. Its purpose is to teach aphasic patients to produce useful phrases by intoning them in a melodic pattern with strong rhythmic support. Limited studies by a few institutions show some benefit for a small number of nonfluent aphasic patients otherwise unresponsive to conventional therapy.

Melodic intonation therapy is a covered service only for nonfluent aphasic patients unresponsive to conventional therapy, and only when the conditions for coverage of speech pathology services are met. Please refer to the Medicare Benefit Policy, Chapter 15, "Covered Medical and Other Health Services," §220; the Medicare Claims Processing Manual, Chapter 5, "Part B Outpatient Rehabilitation and CORF Services," for these conditions of coverage.

170.3 - Speech Pathology Services for the Treatment of Dysphagia

(Rev. 1, 10-01-03)

CIM 35-89

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, or encephalopathies. While dysphagia can afflict any age group, it most often appears among the elderly. Speech pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the

therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-reference:

The Medicare Benefit Policy, Chapter 15, "Covered Medical and Other Health Services," §§220.1 and 230.6.

180 - Nutrition

(Rev. 1, 10-01-03)

180.1 - Medical Nutrition Therapy

(Rev. 1, 10-01-03)

CIM 80-3

Section 1861(s)(2)(V) of the Act authorizes Medicare part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. Regulations for medical nutrition therapy (MNT) were established at 42 CFR 410.130 - 410.134. This national coverage determination establishes the duration and frequency limits for the MNT benefit and coordinates MNT and diabetes outpatient self-management training (DSMT) as a national coverage determination.

Effective October 1, 2002, basic coverage of MNT, for the first year a beneficiary receives MNT, with either a diagnosis of renal disease or diabetes as defined at 42 CFR 410.130 is three hours, of administration. Also, effective October 1, 2002, basic coverage in subsequent years for renal disease or diabetes is two hours. The dietitian/nutritionist may choose how many units are administered per day as long as all of the other requirements in this NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 4CFR 410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

Effective October 1, 2002, if the treating physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 CFR 410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in

medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

180.2 - Enteral and Parenteral Nutritional Therapy

(Rev. 1, 10-01-03)

CIM 65-10

Covered As Prosthetic Device

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

Parenteral Nutrition Therapy

Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than three months by the carrier's medical consultant or specially trained staff, relying on such medical and other documentation as the carrier may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than three months by the contractor's medical consultant or specially trained staff,

and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

190 - Pathology and Laboratory - Not Yet Available

190.1 - Histocompatibility Testing - Not Yet Available

190.2 - Diagnostic Pap Smears - Not Yet Available

190.3 - Cytogenetic Studies - Not Yet Available

190.4 - Electron Microscope - Not Yet Available

190.5 - Sweat Test - Not Yet Available

190.6 - Hair Analysis - Not Yet Available

190.7 - Human Tumor Stem Cell Drug Sensitivity Assays - Not Yet Available

190.8 - Lymphocyte Mitogen Response Assays - Not Yet Available

190.9 - Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS) - Not Yet Available

190.10 - Laboratory Tests - CRD Patients - Not Yet Available

190.11 - Home Prothrombin Time INR Monitoring for Anticoagulation Management - Not Yet Available

200 - Pharmacology

(Rev. 1, 10-01-03)

No coverage determinations

210 - Prevention

(Rev. 1, 10-01-03)

210.1 - Prostate Cancer Screening Tests

(Rev. 1, 10-01-03)

CIM 50-55

Covered

A - General

Section 4103 of the Balanced Budget Act of 1997 provides for coverage of certain prostate cancer screening tests subject to certain coverage, frequency, and payment limitations. Medicare will cover prostate cancer screening tests/procedures for the early detection of prostate cancer. Coverage of prostate cancer screening tests includes the following procedures furnished to an individual for the early detection of prostate cancer:

- Screening digital rectal examination; and
- Screening prostate specific antigen blood test.

B - Screening Digital Rectal Examinations

Screening digital rectal examinations (HCPCS code G0102) are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening digital rectal examination was performed). Screening digital rectal examination means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate. This screening must be performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in §1861(aa) and §1861(gg) of the Act) who is authorized under State law to perform the examination, fully knowledgeable about the beneficiary's medical condition, and would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

C - Screening Prostate Specific Antigen Tests

Screening prostate specific antigen tests (code G0103) are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening prostate specific antigen test was performed). Screening prostate specific antigen tests (PSA) means a test to detect the marker for adenocarcinoma of prostate. PSA is a reliable immunocytochemical marker for primary and metastatic adenocarcinoma of prostate. This screening must be ordered by the beneficiary's physician or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (the term "attending physician" is defined in §1861(r)(1) of the Act to mean a doctor of medicine or osteopathy and the terms "physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife" are defined in §1861(aa) and §1861(gg) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination (test) performed in the overall management of the beneficiary's specific medical problem.

210.2 - Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer

(Rev. 1, 10-01-03)

CIM 50-20.1

Screening Pap Smear

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding three years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every three years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age)
- Multiple sexual partners (five or more in a lifetime)
- History of sexually transmitted disease (including HIV infection)

- Fewer than three negative or any pap smears within the previous seven years; and

- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

NOTE: Claims for pap smears must indicate the beneficiary's low or high risk status by including the appropriate ICD-9-CM on the line item (Item 24E of the Form CMS-1500).

V76.2, special screening for malignant neoplasms of the cervix, **indicates low risk; and**

V15.89, other specified personal history presenting hazards to health, **indicates high risk.**

If pap smear or pelvic exam claims do not point to one of these diagnosis codes, the claim will reject in the Common Working File. Claims can contain up to four diagnosis codes, but the one pointed to on the line item must be either V76.2 or V15.89.

Definitions

- A woman as described in §1861(nn) of the Act is a woman who is of childbearing age and has had a pap smear test during any of the preceding three years that indicated the presence of cervical or vaginal cancer or other abnormality, or is at high risk of developing cervical or vaginal cancer.

- A woman of childbearing age is one who is premenopausal and has been determined by a physician or other qualified practitioner to be of childbearing age, based upon the medical history or other findings.

- Other qualified practitioner, as defined in 42 CFR 410.56(a) includes a certified nurse midwife (as defined in §1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa) of the Act) who is authorized under State law to perform the examination.

Screening Pelvic Examination

Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations. A screening pelvic examination (including a clinical breast examination) should include at least seven of the following eleven elements:

- Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge.

- Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses. Pelvic examination (with or without specimen collection for smears and cultures) including:

- External genitalia (for example, general appearance, hair distribution, or lesions).
- Urethral meatus (for example, size, location, lesions, or prolapse).
- Urethra (for example, masses, tenderness, or scarring).
- Bladder (for example, fullness, masses, or tenderness).
- Vagina (for example, general appearance, estrogen effect, discharge lesions, pelvic support, cystocele, or rectocele).
- Cervix (for example, general appearance, lesions, or discharge).
- Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support).
- Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity).
- Anus and perineum.

This description is from Documentation Guidelines for Evaluation and Management Services, published in May 1997 and was developed by the Centers for Medicare & Medicaid Services and the American Medical Association.

220 - Radiology - Not Yet Available

220.1 - Computerized Tomography - Not Yet Available

220.2 - Magnetic Resonance Imaging - Not Yet Available

220.3 - Magnetic Resonance Angiography - Not Yet Available

220.4 - Mammograms - Not Yet Available

220.5 - Ultrasound Diagnostic Procedures - Not Yet Available

220.6 - Positron Emission Tomography (PET) Scans - Not Yet Available

220.7 - Xenon Scan - Not Yet Available

220.8 - Nuclear Radiology Procedure - Not Yet Available

220.9 - Digital Subtraction Angiography - Not Yet Available

220.10 - Portable Hand-Held X-Ray Instrument - Not Yet Available

220.11 - Thermography - Not Yet Available

220.12 - Single Photon Emission Computed Tomograph (SPECT) - Not Yet Available

220.13 - Percutaneous Image-Guided Breast Biopsy - Not Yet Available

230 - Renal and Genitourinary System - ESRD Services - Not Yet Available

230.1 - Treatment of Kidney Stones - Not Yet Available

230.2 - Uroflowmetric Evaluations - Not Yet Available

230.3 - Sterilization - Not Yet Available

230.4 - Diagnosis and Treatment of Impotence - Not Yet Available

230.5 - Gravlee Jet Washer - Not Yet Available

230.6 - Vabra Aspirator - Not Yet Available

230.7 - Water Purification and Softening Systems Used in Conjunction With Home Dialysis - Not Yet Available

230.8 - Non-Implantable Pelvic Flood Electrical Stimulator - Not Yet Available

230.9 - Cryosurgery of Prostate - Not Yet Available

230.10 - Incontinence Control Devices - Not Yet Available

230.11 - Diagnostic Pap Smears - Not Yet Available

230.12 - Dimethyl Sulfoxide (DMSO) - Not Yet Available

230.13 - Peridex CAPD Filter Set - Not Yet Available

230.14 - Ultrafiltration Monitor - Not Yet Available

230.15 - Electrical Continence Aid - Not Yet Available

230.16 - Bladder Stimulators (Pacemakers) - Not Yet Available

230.17 - Urinary Drainage Bags - Not Yet Available

230.18 - Sacral Nerve Stimulation for Urinary Incontinence - Not Yet Available

230.19 - Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients - Not Yet Available

240 - Respiratory System

(Rev. 1, 10-01-03)

240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)

(Rev. 1, 10-01-03)

CIM 35-93

Reduction pneumoplasty, also called lung shaving or lung contouring, unilateral or bilateral by open or thoracoscopic approach for treatment of emphysema or chronic obstructive pulmonary disease - Not generally covered

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with emphysema and chronic obstructive pulmonary disease (COPD) in order to allow the underlying compressed lung to expand, and thus, establish improved respiratory function. The goal of this procedure is to offer a better quality of life for patients with emphysema and COPD. In addition, LVRS may be offered as a "bridge to transplant" for patients who otherwise may not have been considered candidates for lung transplantation.

Unilateral or bilateral LVRS by open or thoracoscopic approach is not generally covered, because there is insufficient medical evidence available to base a determination that this procedure is generally safe and effective. Therefore, LVRS generally cannot be considered reasonable and necessary under §1862(a)(1)(A) of the Act in most cases.

When this policy was first established in December 1995, CMS committed Medicare to reviewing the scientific literature as it was published in order to modify coverage policy as clinical data were developed. The CMS has reviewed data that suggest the need for a randomized clinical trial regarding the safety and effectiveness of LVRS. On April 24, 1996, CMS and the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health announced their intention to collaborate on a multi-center randomized clinical study evaluating the effectiveness of LVRS. On December 20, 1996, CMS and NHLBI announced the clinical centers and the data-coordinating center that will be participating in the study. The CMS has determined that LVRS is reasonable and necessary when it is provided under the conditions detailed by the protocol of the

CMS/NHLBI clinical study. Therefore, Medicare will cover LVRS in those limited circumstances when it is provided to a Medicare beneficiary under the protocols established for the study. Coverage will be provided where the care is furnished in facilities that are approved as meeting the criteria established by CMS and NHLBI for this study.

This study will consist of a registry of all patients referred to the participating clinical centers for LVRS. In addition, a subset of patients from the registry who meet specific inclusion criteria will be invited to participate in the randomized trial. All randomized patients will receive intensive medical therapy and pulmonary rehabilitation. Half will be selected randomly to undergo LVRS which will be performed via median sternotomy or video-assisted thoracoscopy.

Medicare will provide coverage to those beneficiaries who may participate in the randomized trial for all services integral to the study and for which the Medicare statute does not prohibit coverage. This includes tests performed to determine whether a beneficiary qualifies for randomization, LVRS, and follow-up tests that are necessary during participation in the randomized study. However, Medicare will not provide coverage for those services that are prohibited by the Act. For example, Medicare will provide coverage for pulmonary rehabilitation and pulmonary function testing, but **will not** provide coverage for oral steroids provided as part of a physician's service under §1862(s)(2) of the Act because they are self-administrable and thus statutorily excluded from coverage.

Payment for these services will be provided under the usual payment systems. For example, Part A services will be paid according to the DRG system, and Part B physician services will be paid for according to the physician fee schedule.

The data from the randomized phase of the study will be analyzed and monitored continuously in order to determine any appropriate changes in Medicare coverage. These determinations will include if and how coverage will be continued.

240.2 - Home Use of Oxygen

(Rev. 1, 10-01-03)

CIM 60-4

A - General

Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6)of the Act) is considered reasonable and necessary **only** for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B - Medical Documentation

Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the Form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen **must** also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the carrier's medical staff should review all claims with oxygen flow rates of more than four liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed Form CMS-484. In addition, the supplier or physician may use the space in section C for written confirmation of

additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the carrier in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

Carriers are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations." When indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification **and retesting** of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §100.2.3, for certification and retesting schedules.)

C - Laboratory Evidence

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is **usually** in the form of a measurement of the partial pressure of oxygen (PO_2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending **and** performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines. This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the **initial** claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are, existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than

two days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

Carriers may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a **major** change in their condition relevant to home use of oxygen. If the carrier has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D - Health Conditions

Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e, not during a period of acute illness or an exacerbation of their underlying disease, if:

1. The attending physician has determined that the patient has a health condition outlined in subsection D.1,

2. The patient meets the blood gas evidence requirements specified in subsection D.3, and

3. The patient has appropriately tried other treatment without complete success. (See subsection B.)

1 - Conditions for Which Oxygen Therapy May Be Covered

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or

- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2 - Conditions for Which Oxygen Therapy Is Not Covered

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;

- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;

- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO_2 improves the oxygenation of tissues with impaired circulation; or

- Terminal illnesses that do not affect the lungs.

3 - Covered Blood Gas Values

If the patient has a condition specified in subsection D.1, the carrier must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

(a) - Group I - Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by **any** of the following:

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, **taken at rest**, breathing room air.

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken **during sleep** for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level **during sleep** (a decrease in arterial PO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided **only** for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen ,therefore, would not be covered in this situation.

- An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken **during exercise** for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for **during exercise** if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

(b) - Group II - Except as modified in subsection d, coverage is available for patients whose arterial PO_2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, **if** there is evidence of:

- Dependent edema suggesting congestive heart failure;

- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or

- Erythrocythemia with a hematocrit greater than 56 percent.

(c) - Group III - Except as modified in subsection d, carriers must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO_2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent. In order for claims in this category to be reimbursed, the carrier's reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims. The CMS expects few claims to be approved for coverage in this category.

(d) - Variable Factors That May Affect Blood Gas Values - In reviewing the arterial PO_2 levels and the arterial oxygen saturation percentages specified in subsections D.3.a, b, and c, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E - Portable Oxygen Systems

A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A-D, as appropriate; and

- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep

F - Respiratory Therapists

Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B durable medical equipment benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §280.1, and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110)

240.3 - Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions

(Rev. 1, 10-01-03)

CIM 35-3

Not Covered

There is no physiological rationale or valid scientific documentation of effectiveness of diathermy or ultrasound heat treatments for asthma, bronchitis, or any other pulmonary condition and for such purpose this treatment cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

Cross-reference: §150.5.

240.4 - Continuous Positive Airway Pressure (CPAP)

(Rev. 1, 10-01-03)

CIM 60-17

CPAP is a noninvasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep which occurs in obstructive sleep apnea (OSA).

The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of recorded sleep. The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP.

Initial claims must be supported by medical documentation (separate documentation where electronic billing is used), such as a prescription written by the patient's attending physician, that specifies:

- A diagnosis of moderate or severe obstructive sleep apnea, and
- Surgery is a likely alternative.
- The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available.

The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the following criteria using the Apnea-Hyopopnea Index (AHI) are met:

- AHI $\geq$ 15 events per hour, or

- AHI ≥ 5 and ≤ 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

The AHI is equal to the average number of episodes of apnea and hyponea per hour and must be based on a minimum of two hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation.

The polysomnography must be performed in a facility - based sleep study laboratory, and not in the home or in a mobile facility.

Initial claims for CPAP devices must be supported by information contained in the medical record indicating that the patient meets Medicare's stated coverage criteria.

Cross References: §280.1.

240.5 - Intrapulmonary Percussive Ventilator (IPV)

(Rev. 1, 10-01-03)

CIM 60-21

Not Covered

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient's chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

240.6 - Transvenous (Catheter) Pulmonary Embolectomy

(Rev. 1, 10-01-03)

CIM 35-55

Not Covered

Transvenous (catheter) pulmonary embolectomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein. It is not covered under Medicare because it is still experimental.

240.7 - Postural Drainage Procedures and Pulmonary Exercises

(Rev. 1, 10-01-03)

CIM 35-15

In most cases, postural drainage procedures and pulmonary exercises can be carried out safely and effectively by nursing personnel. However, in some cases patients may have acute or severe pulmonary conditions involving complex situations in which these procedures or exercises require the knowledge and skills of a physical therapist or a respiratory therapist. Therefore, if the attending physician determines as part of his/her plan of treatment that for the safe and effective administration of such services the procedures or exercises in question need to be performed by a **physical therapist**, the services of such a therapist constitute covered physical therapy when provided as an inpatient hospital service, extended care service, home health service, or outpatient physical therapy service.

NOTE: Physical therapy furnished in the outpatient department of a hospital is covered under the outpatient physical therapy benefit.

If the attending physician determines that the services should be performed by a **respiratory therapist,** the services of such a therapist constitute covered respiratory therapy when provided as an inpatient hospital service, outpatient hospital service, or extended care service, assuming that such services are furnished to the skilled nursing facility by a hospital with which the facility has a transfer agreement. Since the services of a respiratory therapist are not covered under the home health benefit, payment may not be made under the home health benefit for visits by a respiratory therapist to a patient's home to provide such services. Postural drainage procedures and pulmonary exercises are also covered when furnished by a physical therapist or a respiratory therapist as incident to a physician's professional service.

Cross references:

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20.

The Medicare Benefit Policy Manual, Chapter 7, “Home Health Services,” §20.

The Medicare Benefit Policy Manual, Chapter 8, “Coverage of Extended Care (SNF) Services Under Health Insurance,” §50.

The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §60.2.

250 - Skin

(Rev. 1, 10-01-03)

250.1 - Treatment of Psoriasis

(Rev. 1, 10-01-03)

CIM 35-66

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The contractor should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

250.2 - Hemorheograph

(Rev. 1, 10-01-03)

CIM 50-16

The hemorheograph is a diagnostic instrument which is safe and effective for determining the adequacy of skin perfusion prior to the performance of minor surgical procedures on the extremities, including minor podiatric procedures, and as an adjunct to the evaluation of patients suspected of having peripheral vascular disease.

Program payment may be made only for those services employing the hemorheograph which are performed for preoperative and postoperative diagnostic evaluation of suspected peripheral artery disease.

NOTE: This instrument is not a plethysmograph and is not considered as such. A plethysmograph measures and records changes in the size of a body part as modified by the circulation of blood in that part. The hemorheograph, on the other hand, measures surface blood flow in the skin; it does not measure total blood flow in a digit or limb.

250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucutaneous Blistering Diseases

(Rev. 1, 10-01-03)

CIM 45-31

Intravenous immune globulin (IVIg) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents.

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven: (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

- Patients who have failed conventional therapy. Contractors have the discretion to define what constitutes failure of conventional therapy;

- Patients in whom conventional therapy is otherwise contraindicated. conventional therapy; or

- Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. Contractors have the discretion to decide what constitutes short-term therapy.

HCPCS code pending	Long description pending

250.4 - Treatment of Actinic Keratosis

(Rev. 1, 10-01-03)

CIM 35-101

Actinic keratoses (AKs), also known as solar keratoses, are common, sun-induced skin lesions that are confined to the epidermis and have the potential to become a skin cancer.

Various options exist for treating AKs. Clinicians should select an appropriate treatment based on the patient's medical history, the lesion's characteristics, and on the patient's preference for a specific treatment. Commonly performed treatments for AKs include cryosurgery with liquid nitrogen, topical drug therapy, and curettage. Less commonly performed treatments for AK include dermabrasion, excision, chemical peels, laser therapy, and photodynamic therapy (PDT). An alternative approach to treating AKs is to observe the lesions over time and remove them only if they exhibit specific clinical features suggesting possible transformation to invasive squamous cell carcinoma (SCC).

Effective for services performed on and after November 26, 2001, Medicare covers the destruction of actinic keratoses without restrictions based on lesion or patient characteristics.

260 - Transplantation - Solid Organ Transplants - Not Yet Available

260.1 - Adult Liver Transplantation - Not Yet Available

260.2 - Pediatric Liver Transplantation - Not Yet Available

260.3 - Pancreas Transplants - Not Yet Available

260.4 - Reserved

260.5 - Intestinal and Multi-Visceral Transplantation - Not Yet Available

260.6 - Dental Examination Prior to Kidney Transplantation - Not Yet Available

260.7 - Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) - Not Yet Available

260.8 - Reserved

260.9 - Heart Transplants - Not Yet Available

270 - Wound Treatment - Not Yet Available

270.1 - Electrostimulation in the Treatment of Wounds-Not Covered - Not Yet Available

270.1.1 - Electrical Stimulation for the Treatment of Wounds - Not Yet Available

270.2 - Noncontact Normothermic Wound Therapy (NNWT) - Not Yet Available

270.3 - Platelet-Derived Wound Healing Formula - Not Yet Available

270.4 - Treatment of Decubitus Ulcers - Not Yet Available

270.5 - Porcine Skin and Gradient Pressure Dressings - Not Yet Available

280 - Medical and Surgical Supplies - Not Yet Available

280.1 - Durable Medical Equipment Reference List - Not Yet Available

280.2 - White Cane for Use by a Blind Person - Not Yet Available

280.3 - Specially Sized Wheelchairs - Not Yet Available

280.4 - Seat Lift - Not Yet Available

280.5 - Safety Roller - Not Yet Available

280.6 - Pneumatic Compression Devices - Not Yet Available

280.7 - Hospital Beds - Not Yet Available

280.8 - Air-Fluidized Bed - Not Yet Available

280.9 - Power Operated Vehicles That May Be Used as Wheelchairs - Not Yet Available

280.10 - Prosthetic Shoe - Not Yet Available

280.11 - Corset Used as Hernia Support - Not Yet Available

280.12 - Sykes Hernia Control - Not Yet Available

280.13 - Transcutaneous Electrical Nerve Stimulators (TENS) - Not Yet Available

280.14 – Infusion Pumps - Not Yet Available

290 - Nursing Services - Not Yet Available

290.1 - Home Health Visits to a Blind Diabetic - Not Yet Available

290.2 - Home Health Nurses' Visits to Patients Requiring Heparin Injections - Not Yet Available

300 - Diagnostic Tests Not Otherwise Classified - Not Yet Available

300.1 - Obsolete or Unreliable Diagnostic Tests - Not Yet Available

310 - Clinical Trials

(Rev. 1, 10-01-03)

310.1 - Routine Costs in Clinical Trails

(Rev. 1, 10-01-03)

CIM 30-1

Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial **except:**

- The investigational item or service, itself;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);

- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201 - 405.215, 411.15, and 411.406. For information about local medical review policies (LMRPs), refer to http://www.lmrp.net/, a searchable database of Medicare contractors' local policies.